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October 2, 2003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re/ Application of Z. Saidi and B. Klyashchitsky

Application No. 10/019,100

Filed December 20, 2001

Examiner: Not Yet Assigned

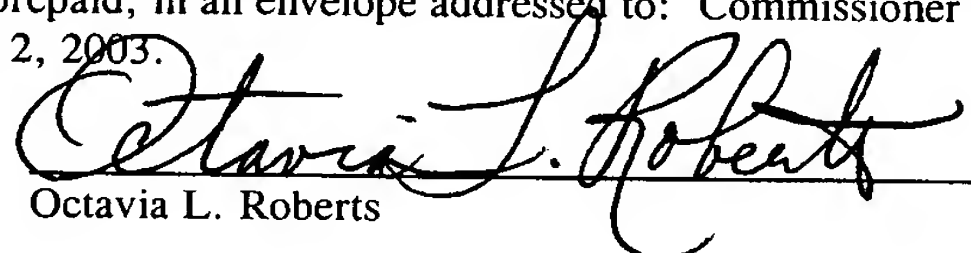
Group Art Unit: Not Yet Assigned

**AQUEOUS COMPOSITIONS CONTAINING CORTICOSTEROIDS  
FOR NASAL AND PULMONARY DELIVERY**

(Attorney Docket No. P24,800-A USA)

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence, along with any other papers indicated as being enclosed, is being deposited with the United States Postal Services, as first class mail, postage prepaid, in an envelope addressed to: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 on October 2, 2003.

  
Octavia L. Roberts

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 CFR §1.97(B)**

Sir:

It is requested respectfully that the information identified on the enclosed Form PTO-1449 (Modified) be made of record and considered with respect to the above-referenced patent application. The Examiner is requested to indicate that each item on the enclosed Form PTO-1449 (Modified) has been considered by initialing and dating the enclosed Form and returning a copy of same to the undersigned.

Group Art Unit: Not Assigned Yet  
Application No. 10/019,100

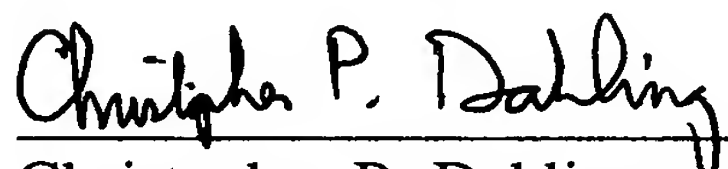
October 2, 2003  
Docket No. P24,800-A USA

This Information Disclosure Statement is filed before a first Office Action on the merits. The above-referenced patent application is a Continuation-in-Part of U.S. Patent Application Serial No. 09/105,838 filed June 26, 1998, now U.S. Patent No. 6,241,969. The publications listed on the Form PTO-1449 were cited by or submitted to the Patent Office during the pendency of the parent application. Copies of such publications are not provided as permitted by 37 C.F.R. §1.98(d).

Identification of information on the attached Form, or in this statement, is not an admission that such information is prior art to the invention claimed in the present application or that such information is in an analogous art area.

The Commissioner is authorized hereby to charge any fees or credit any overpayment associated with this Statement (copy enclosed) to Deposit Account Number 19-5425.

Respectfully submitted,

  
\_\_\_\_\_  
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FORM PTO-1449 (MODIFIED)

ATTORNEY DOCKET NO.

APPLICATION NO.

P24,800-A USA

10/019,100

LIST OF PATENTS AND OTHER  
PUBLICATIONS FOR APPLICANT'S  
INFORMATION DISCLOSURE STATEMENT  
(USE SEVERAL SHEETS IF NECESSARY)

APPLICANT

Z. Saidi and B. Klyashchitsky

FILING DATE

December 20, 2001

GROUP ART UNIT

NYA

U.S. Department of Commerce  
Patent and Trademark Office

## U.S. PATENT DOCUMENTS

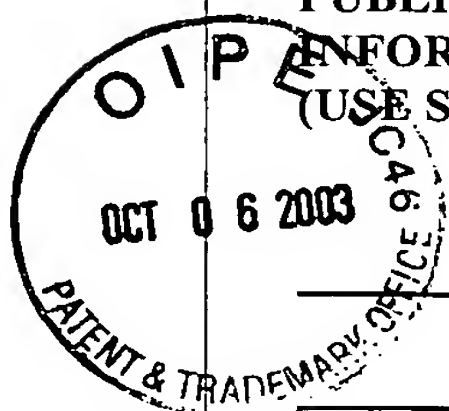
EXAMINER INITIALS		DOCUMENT NO.	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA	4,073,943	02/14/1978	Wretlind et al.	424	358	03/12/1976
	AB	4,567,161	01/28/1986	Posanski et al.	514	23	06/28/1983
	AC	4,782,047	11/01/1988	Benjamin et al.	514	174	05/22/1986
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	AJ	5,478,860	12/26/1995	Wheeler et al.	514	449	06/04/1993
	AK	5,496,811	03/05/1996	Aviv et al.	514	78	01/05/1993


## FOREIGN PATENT DOCUMENTS

EXAMINER INITIALS		DOCUMENT NO.	DATE	COUNTRY
	BA	2083927	12/11/1993	CA

## OTHER PUBLICATIONS

	CA	Bochner et al., "Immunological Aspects of Allergic Asthma," <u>Annu. Rev. Immunol.</u> , <u>12</u> , 295-335 (1994)
	CB	Brain, et al., "Aerosols: Basics and Clinical Considerations," <u>Bronchial Asthma</u> , Second Edition, Weiss, E.B. et al., (eds.), Little, Brown and Company, 594-603 (1985)
	CC	Eastman Chemical Company, "Eastman Vitamin E TPGS: Properties and Applications," <u>Pharmaceutical Ingredients</u> , 1-21 (Oct. 1996)
	CD	Goodman & Gilman's, "The Pharmacological Basis of Therapeutics," Ninth Edition, McGraw-Hill, 662-664, 666-667, 1470-1471, 1473, 1480 (1996)
	CE	Klyashchitsky et al., "Drug Delivery Systems for Cyclosporine: Achievements and Complications," <u>J. Drug Targeting</u> , <u>5(6)</u> , 443-458 (1998)
	CF	Klyashchitsky et al., "Nebulizer-Compatible Liquid Formulations for Aerosol Pulmonary Delivery of Hydrophobic Drugs: Glucocorticoids and Cyclosporine," <u>J. Drug Targeting</u> , <u>7(2)</u> , 79-99 (1999)
	CG	Ly et al., "Evaluation and Application of Hydrophilic Tocopherol Polyethylene Glycol Derivatives as Enhancers of Drug Solubility," College of Pharmacy and Allied Health Professions, St. John's University, Jamaica, NY, Presentation ID: 3419, Nov. 5, 1997, 1 page summary.
	CH	Ly, et al., "Evaluation of (+)- $\alpha$ -Tocopherol Polyethylene Glycol 1000 (TPG) as an Enhancer of Drug Solubility in Aqueous Solution," <u>Proc. 2<sup>nd</sup> World Meeting APGI/APV</u> , Paris, May 25/28, 1-2 (1998)





CI	Pavord et al., "Pharmacokinetic Optimization of Inhaled Steroid Therapy in Asthma," <u>Clin. Pharmacokinet.</u> , <u>25</u> (2), 126-135 (1993)
CJ	Schreier et al., "Pulmonary Delivery of Liposomes," <u>J. Control. Release</u> , <u>24</u> , 209-223 (1993)
CK	Waldrep, et al., "High dose Cyclosporin A and Budesonide-liposome aerosols," <u>Intl. J. Pharm.</u> , <u>152</u> (1), 27-36 (1997)
CL	Waldrep, et al., "Nebulized Glucococorticoids in Liposomes: Aerosol Characteristics and Human Dose Estimates," <u>J. Aerosol Medicine</u> , <u>7</u> (2), 135-145 (1994)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformation *and* not considered. Include copy of this form with next communication to applicant.

Sheet 2 of 2

October 2, 2003